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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/020,881 | 12/19/2001 | Sheldon Tobe | PT-1950001 | 8794 |

23607 7590 12/28/2004

IVOR M. HUGHES, BARRISTER & SOLICITOR,
PATENT & TRADEMARK AGENTS
175 COMMERCE VALLEY DRIVE WEST
SUITE 200
THORNHILL, ON L3T 7P6
CANADA

EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,881

Applicant(s)

TOBE, SHELDON

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-10 and 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/16/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant is advised that this application has been transferred to Technology Center 1600 and this Examiner in Art Unit 1616 based on the restriction requirement of 6/28/2004 and applicant election of 8/13/2004.

Claims 1-20 are pending in this application.

Applicant's election with traverse of the invention of Group I, claims 1 and 11, in the reply filed on 8/13/2004 is acknowledged. The traversal is an incorporation of applicant's response of 4/15/2004. This traversal was fully addressed by the previous Examiner in the second restriction requirement, which was mailed on 6/28/2004.

Applicant also states that "it makes little sense to group dependent claims apart from their corresponding independent inventions." This is not found persuasive, because a restriction into several inventions is not precluded by the fact that various dependent claims (directed to distinct inventions) ultimately refer back to the same independent claim. If this were not the case, a little bit of creative claim drafting would void any and all future restriction requirements. The test for the propriety of a restriction has always been the dual test of independence/distinctness and undue burden. Having met both of these requirements, as fully set forth by the previous Examiner in the two previous restriction requirement Office actions, the requirement is still deemed proper and is therefore made FINAL.

Claims 2-10, 12-20 are withdrawn from further consideration as being directed to non-elected subject matter. Claims 1 and 11 will presently be examined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Purcell et al. (US 5,945,449).

Purcell et al. explicitly disclose a sterile concentrate suitable for peritoneal dialysis and hemofiltration, which contains, inter alia, 86.67 ± 8.6 g/l of sodium chloride and 2.05 ± 0.2 g/l of magnesium chloride (column 5, lines 20-37).

Applicant's claim 1 requires "a sterile dialysis concentrate" comprising 92.30 ± 9.2 g/l of sodium chloride and 2.05 ± 0.2 g/l of magnesium chloride. Applicant's claim 1 is thereby clearly anticipated by the explicit disclosure of Purcell et al.

Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Fischbach (US 6,251,437).

Fischbach explicitly discloses a hemodialysis solution component that contains, inter alia, 153-289 g/l of sodium chloride and 1-8 g/l of magnesium chloride (column 6, lines 42-54; see claims 1, 5 and 8).

Applicant's claim 1 requires "a sterile dialysis concentrate" comprising 211.96 ± 21 g/l of sodium chloride and 4.72 ± 0.4 g/l of magnesium chloride. Fischbach's component amounts clearly encompass and anticipate the claimed amounts. As for the "sterile" claim feature, it is the Examiner's position that because Fischbach's composition is intended for hemodialysis, the sterile feature would have been necessarily present in Fischbach's composition. The claims are thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischbach (US 6,251,437).

Fischbach explicitly discloses a hemodialysis solution component that contains, inter alia, 153-289 g/l of sodium chloride and 1-8 g/l of magnesium chloride (column 6, lines 42-54; see claims 1, 5 and 8).

Applicant's claim 1 requires "a sterile dialysis concentrate" comprising 211.96 ± 21 g/l of sodium chloride and 4.72 ± 0.4 g/l of magnesium chloride. Fischbach's component amounts clearly teaches the claimed amounts. As for the "sterile" claim feature, it is the Examiner's position that because Fischbach's composition is intended for hemodialysis, the sterile feature would have been necessarily present in Fischbach's composition. The claims are thereby anticipated. *In the alternative*, sterilizing Fischbach's composition would have been an obvious step for the ordinary skilled artisan, who would have been motivated by safety concerns in delivering dialysis therapy to already compromised and vulnerable patients.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

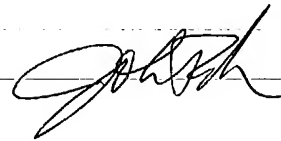
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**JOHN PAK
PRIMARY EXAMINER
GROUP 1200**